Requirements Specification

Improving Repository Incoming Shipments Workflow

ICEBERG Biorepository & Systems Interoperability Working Groups
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Background

Part of the scope of the Biorepository & Systems Interoperability Working Groups is to develop data and systems interoperability standards to enable more efficient workflow processes among biorepository informatics systems. This document is a requirements specification to improve the repository workflow for specimen receipt.

Four major factors drive this effort:

1. The number of vials in the BSI system has increased by 230% in the last 5 years (as of April 2004). This rate of increase is expected to further increase dramatically as the the implementation high-throughput molecular methods become more common, like gene expression micro arrays and large scale DNA extractions.
2. The number of requisitions processed by the repositories has doubled in the last five years, with sustained growth expected.
3. There is not a proportional increase in repository funding to support these trends, thus efficiencies must be found elsewhere to balance this increased demand for service.
4. A recent empirical study has measured the time taken for a repository to inventory and store a box of 81 vials with no prior notification, electronic manifests, and barcoded labels. The time was found to be ten times greater than when processing an incoming box with all of those attributes.

Applying technology to improve and automate the sample processing workflow is therefore an essential component to meeting the increasing demands on the repositories. The major DCEG contractors have several systems that are used in the collection, processing, and storage of specimens. However, with very few exceptions these systems do not yet communicate with each other, requiring repository staff to perform manual and error prone steps to transfer data from one system to another. Significant efficiency gains can be realized by better integrating these systems.

Goals

1. Increase the efficiency of specimen receipt workflows by promoting system interoperability to reduce required labor.
2. Promote and facilitate use of ubiquitous electronic manifests and barcoding as both better quality control and time-saving mechanisms.
3. Provide additional automated communication between the field sites, repositories,

investigators and contractors to keep all interested parties informed of newly collected specimen status.

Requirements

D. Communication

1. Early notification of incoming shipments is essential to improving the repository workflow. These notifications may come from two primary sources: from a shipping carrier's web services application or via a custom shipment web site (discussed below). Since the information provided by a carrier's web service may be limited to the date shipped and tracking number, this section on communication assumes that the information is coming from a web site that can provide supplemental information. In the cases when the only notification comes from a carrier's web service, the repository staff will have the option of either entering the data into the shipping web site or directly into BSI.
2. Prompt notification of incoming shipments from field sites to the repository is required. These notifications should include the following data:
    a. Field site ID
    b. Carrier
    c. Tracking ID
    d. Study ID
    e. Field contact name (optional)
    f. Number of boxes (optional)
    g. Temperature (optional)
    h. Electronic manifest (optional)
3. All interested parties must receive notification when a shipment is sent. The information included in the notification will be from the list above.
4. All interested parties must receive notification when a shipment is received by the repository. In addition to the list above the information should include the condition of the shipment when it was received.
5. All interested parties must receive notification when the shipment is inventoried. Information will include:
    a. Field site ID
    b. Carrier
    c. Tracking ID
    d. Study ID
    e. Exact specimen count
    f. A list of any discrepancies in the shipment
6. All interested parties must receive notification when discrepancies are resolved.
7. At well defined time intervals, all interested parties must receive a list of outstanding discrepancies for a shipment.
8. All interested parties must receive notification when shipment data is finally committed to BSI.

E. Field Site Data Collection

A critical aspect in improving the sample processing workflow is the collection and exchange of electronic specimen data. Electronic data collection should be utilized as early as possible, preferably at the field site that collects the specimen. This data could then be sent to the repository, eliminating repository redundant data entry and the possible introduction of additional transcription errors. While some field sites have data systems available to them, others do not. What is needed is a data collection system that can be distributed to the field sites to promote early data collection. This application must:

1. Be intuitive and easy to use. This reduces the training burden and frustration level for the field site's staff.
2. Have an interface that is customizable to a particular study's needs.
3. Provide for automated data generation to reduce the field site's data entry burden.
4. Scale to accommodate both small and large studies as well as single- and multi-user environments.
5. Provide data verification capabilities to perform proactive edit checks during data entry.
6. Provide automatic communication and data transmission via the Internet (direct or dialup) with the BSI Web services (described below) for communicating shipment data to the repository.
7. Provide alternative methods (diskette/flash-device/fax) of transferring data to the repository when a direct Internet connection is not available.

If a system already exits at a field site to collect this data, it should be feasible to modify it to submit the sample data via the BSI Web services or export the data into a format readable by BSI or BSI Translate.

Implementation note: Westat already has a Study Management System (SMS) that may have components that meet most of these requirements.

F. Shipment Web Site

A customized web site should be created to capture detailed shipment information. This Web site must:

1. Support entry of the shipment data fields noted above.
2. Provide authenticated and secure data transmission.
3. Be intuitive and easy to use.
4. Provide a mechanism to transmit electronic shipment manifests.

Implementation note: RTI already has a web site for a study that might be expanded to

meet these requirements. Alternatively, the BSI Web interface could also be enchanced to provide this capability.

G. Electronic Manifests and Barcodes

The use of electronic manifests and barcoded labels are essential in order to maximize repository productivity. Their use should be strongly encouraged, and systems should be tailored to optimize for shipments with these components.

1. Bar coding of specimens is a requirement for for optimal workflow efficiency.
2. Electronic manifests are also required. Submission of manifest should be possible
    a. Shipment web site (noted above)
    b. Email
    c. Diskette/flash device

H. Modifications to BSI

Supporting an improved incoming shipment workflow will also require improvements to the BSI system. These new features are needed:

1. The development of an incoming shipments module to provide storage, management, and tracking of incoming shipments before the specimens are committed into the database via data entry batches. The module will also provide the ability to:
    a. scan specimens in shipment for presence and condition.
    b. auto-assign freezer positions.
    c. reserve BSI Ids, freezer locations, and other critical unique data for specimens in an incoming shipment but not committed to the database yet.
    d. track the existence and the resolution of discrepancies.
        i. Addition of two new discrepancy fields to vial table
        ii. Submission of partial batches of non-discrepant specimens
2. Addition of a shipment ID field to vial table in order to associate a specimen with it's incoming shipment information.
3. Incorporation of BSI Translate into the data entry module for customized automatic data reformatting.
4. An enhanced notification system to broadcast events to interested parties regarding changes in specimen status.

I. BSI Web Services

A web services layer needs to be implemented to provide automated access to the BSI transaction server and database. This web services layer must provide:

1. Automatic creation of incoming shipment batches.
2. Transmission of electronic manifests.
3. Queries on shipment processing status.
4. Queries of sample inventory by relevant search criteria.

Implementation note: The BSI Web services layer will also provide an API for automated data exchange between BSI and the CGF LIMS system, as well as access for NCI's Study Dashboard.

J. BSITrack

This application was discussed in abstract at several meetings as an automatic electronic secretary that would:

1. Polling specimen carrier's web sites and web services interfaces to detect changes in tracking status and notify interested parties.
2. Provide notifications to interested parties of specimen-related events as they are published by different data systems. Examples could include:
    a. Receipt of a BSI shipment batch.
    b. Successful commit of a data entry batch into the BSI.
    c. Completion of DNA extraction by CGF or ATCC.
    d. Shipment of specimens from BSI or other specimen system.

Implementation note: While this concept started as BSI centric, its scope could be expanded to a generic study tracking/notification system where any data system could publish or register a notification event. This should be the subject of it's own requirements gathering/analysis effort.